UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF OHIO
WESTERN DIVISION

JUDY WETHINGTON, *et al.*,	:	
	:	Case No. 1:01cv441
Plaintiffs,	:	
	:	Judge S. Arthur Spiegel
v.	:	
	:	
PURDUE PHARMA, L.P., *et al.*,	:	
	:	
Defendants.	:	

PURDUE DEFENDANTS' REPLY MEMORANDUM IN SUPPORT OF MOTION TO STRIKE

PRELIMINARY STATEMENT

Plaintiffs' reliance on the Zakrzewski complaint has been gutted by Zakrzewski's dismissal of that complaint. Accordingly, the Court should dispose quickly of the Plaintiffs' latest submission, grant the Defendants' motion to strike, and deny Plaintiffs' motion for reconsideration.

Zakrzewski aside, nothing in Plaintiffs' recent submission changes the predominating impact of individual issues and the learned intermediary doctrine. Nothing Plaintiffs submit or argue alters this Court's previous analysis that "Plaintiffs' claims are inherently individualized requiring an inquiry into questions of fact and law peculiar to each class member." Wethington v. Purdue Pharma, 218 F.R.D. 577, 590 (S.D. Ohio 2003).

ZAKRZEWSKI

Attached is the voluntary dismissal that Zakrzewski filed on February 3, 2004 -- *prior* to Plaintiffs' latest submission advising this Court that the lawsuit was proceeding (see

Plaintiffs' Opposition Memorandum in Response to Purdue Defendants' Motion to Strike, fn 1). Nothing can speak more forcefully about the risk of reconsidering an order denying class certification on the basis of unsworn allegations in an amended complaint. Not only were they merely allegations in the first place, now they are not even that.

GAO REPORT

Plaintiffs selectively attach 4 pages of a 63-page report issued by GAO. On one and a half of those pages the report discusses two promotional videos that were discontinued nearly three years ago, after labeling changes were instituted (additionally, one video was not available until after February 1999, while the second was not available until after 2000 -- both well after the December 1995 trigger date Plaintiffs used to define their proposed class).

Plaintiffs' insistence that isolated statements plucked from the GAO report somehow support their motion to reconsider the denial of class certification is fundamentally flawed. First, there was no finding that Purdue had engaged in any "deceptive conduct" as Plaintiffs argue. While Purdue acknowledged its oversight of not timely submitting the first version of the 1998 video (which video was not made available for distribution to physicians until February 1999), GAO noted that Purdue timely submitted the second version. Likewise, both versions of the 2000 video discussed by GAO were also timely submitted to FDA; although FDA did not review any of the videos for enforcement purposes. Second, and irrespective of whether the 1998 video was timely submitted or whether claims made in the video were or were not substantiated, Plaintiffs' argument that the GAO statements about the video present a basis for this Court to reconsider its denial of class certification is wrong. Not only do Plaintiffs ignore the critical fact that eight of the ten Plaintiffs here were first prescribed OxyContin *before*

the video was available to be distributed to physicians[1] (or that GAO stated that only 15,000 copies were distributed to physicians nationwide (representing fewer than 10% of the physicians in Purdue's physician database)), but as this Court noted in Harris v. Purdue Pharma, 218 F.R.D. 590, 596 (S.D. Ohio 2003), the "existence of individual Learned Intermediaries trumps any common marketing issues." In other words, each Plaintiff would have to prove that his or her physician *saw* the defunct video in question prior to prescribing OxyContin to him or her, and was

> "deceived as to the efficacy, danger, or proper use of the drug, or any combination of those three things. Next, Plaintiff would need to demonstrate whether the physician, as a result of the deception, improperly prescribed the drug to an individual patient . Finally, each Plaintiff would have to demonstrate that he or she was injured by an increased risk of addiction, having been improperly prescribed or refilled the medication."

Id. As this Court properly concluded in Harris, "[t]his entire inquiry is highly individualized." Id. Hence, the GAO report provides no basis for Plaintiffs to seek reconsideration of the order denying class certification.

THE *ENDO* DECISION

Purdue has appealed the Endo[2] decision, which found first that the patents for OxyContin® had been infringed and second, that they were unenforceable due to "inequitable conduct"-- a term of art in patent law -- before the Patent and Trademark Office.[3] Absent from

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[1] Plaintiffs Sylvia Bingham, David Wethington, Robert Schell, Beverly Schwalm, Karen Eicher, James Thornbury, Ronald Farris and Michael Younger all received their first OxyContin prescriptions in either 1996, 1997 or 1998 -- the video discussed by GAO was not first distributed until February 1999.

[2] Purdue Pharma L.P. v. Endo Pharmaceuticals Inc., No. 01 Civ. 8029, 2004 WL 26523 (S.D.N.Y. Jan. 5, 2004).

[3] Plaintiffs again misstate the law when they advise this Court that the Endo decision "demonstrates that Purdue engaged in fraudulent conduct" or committed an "unconscionable" act. "Inequitable conduct" -- as found by the Endo Court -- is a term that has meaning only within the context of patent law. The Federal Circuit (which sits in review of all patent law decisions) has repeatedly held that a finding of "inequitable conduct" is not the same as a finding of fraud. See e.g., Ulead Sys., Inc.v. Lex Computer & Mgmt. Corp., 351 F.3d 1139, 1144 (Fed. Cir. 2003).

Plaintiffs' rendition of what the Endo decision states is the fact that the Endo Court specifically found that Purdue's scientific discovery at issue in the patent infringement action (concerning dosing ranges) was *true* -- "[a]ccordingly, Purdue has proven that the patents in suit adequately control pain for approximately 90% of patients within a four-fold dosage range." Purdue Pharma v. Endo Pharmaceuticals, No. 01 Civ. 8029, 2004 WL 26523, at *17 (S.D.N.Y Jan. 5, 2004)

With respect to any application to the product liability case at bar here, the Endo opinion has nothing to do with the safety or efficacy of OxyContin® or with FDA approval of it. No part of the FDA approval process depends on the enforceability of Purdue's patents or statements made to the Patent and Trademark Office. Moreover, the Endo opinion has nothing to do with information provided physicians -- that has always been grounded in the FDA-approved package insert. Thus, the patent decision can have no impact on each patient's individual medical, social, family and lifestyle history (including concurrent or previous use of other opioids and prescription pain medications), each doctors' testimony about his or her discussions with each patient, each doctor's individual treatment of the particular patient, or any of the other multitude of individual factors that informed the OxyContin treatment decisions (not to mention whether there was any resulting harm *caused* by the OxyContin treatment) concerning each particular patient.

CONCLUSION

For the foregoing reasons and those previously stated, the Court should strike Exhibit A and deny Plaintiffs' motion to reconsider.

Respectfully submitted,

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in the above entitled action is withdrawn.

SIGNATURE REQUIRED

Plaintiff Marek Zakrzewski ; By [signature] Victoria de Toledo Attorney
Plaintiff ____ ; By ____ Attorney
Defendant ____ ; By ____ Attorney
Defendant ____ ; By ____ Attorney

NAME & ADDRESS OF SIGNER: Victoria de Toledo, Casper & de Toledo, 1458 Bedford Street, Stamford, CT 06905

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